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IS/ISO 8362-1 (2003): INJECTION CONTAINERS AND ACCESSORIES, PART 1: INJECTION VIALS MADE OF GLASS TUBING [MHD 10: Medical Laboratory Instruments]

Act Number 22 of 2005
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[Superseding IS 1984 (Part 1) : 2003]

भारतीय मानक

इन्जेक्शन हेतु आधान और उपसाधन

भाग 1 काँच की नलियों से बनी इन्जेक्शन वायल्स

Indian Standard

INJECTION CONTAINERS AND ACCESSORIES

PART 1 INJECTION VIALS MADE OF GLASS TUBING

ICS 11.040.20

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 2

Medical Laboratory Instruments Sectional Committee, MHD 10

NATIONAL FOREWORD

This Indian Standard (Part 1) which is identical with ISO 8362-1 : 2003 'Injection containers and accessories — Part 1: Injection vials made of glass tubing' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Medical Laboratory Instruments Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published as IS 1984 (Part 1) : 1961 and revised in 1971 to incorporate modifications in respect of limits of alkalinity, uniformity in dimensions of neck finished, closer dimensional tolerances and merger of the requirements for vaccine phials covered earlier under IS 490 : 1967 'Specification for vaccine phials (*first revision*)'. It was revised in 2003 with a view to align it with ISO 8362-1 : 1989. This standard has been brought out with a view to align its requirements with ISO 8362-1 : 2003. After the publication of this standard IS 1984 (Part 1) : 2003 'Injection containers for injectables and accessories: Part 1 Injection vials made of glass tubing (*second revision*)' shall be treated as withdrawn. IS 1984 (Part 2) : 2003 'Injection containers for injectables and accessories: Part 2 Injection vials made of moulded glass (*second revision*)' was also published for injection vials made of moulded glass.

The purpose of this part of standard is to specify the dimensions, capacities, form and requirements of glass vials intended for medical use. Containers made from glass tubing are considered to be suitable for the packaging and storage of injectable preparations until they are administered for medicinal purposes. Such containers may be made from different types of glass, which can affect the chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance, whereas others made from soda-lime-silica glass will have a lower, but adequate, chemical resistance for the purpose for which they are intended. The chemical resistance of the internal surface of containers made from soda-lime-silica glass can be improved by the treatment during production to produce a chemical resistanc equal to that of those made from borosilicate glass for single use. This level of chemical resistance will be maintained as long as the interior surface is not destroyed by chemical resistance will be maintained as long as the interior surface is not destroyed by chemical attack, in which case it will be reduced to that of untreated soda-lime glass.

Because containers may be made from different types of glass and because it is the chemical behaviour of the internal surface, which is important when they are filled with injectable preparations, it is essential to specify test procedures by which this performance can be measured. The procedures recommended in this part of the standard will allow this performance based on the hydrolytic resistance, to be measured and, from the result of measurement, it is possible to classify containers into their correct category. The procedure also allows containers to be tested and to determine, after an intermediate stage, whether the hydrolytic resistance is produced by the composition of the glass as a material or by a treatment of the internal surface.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker in the International Standard while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

(*Continued on third cover*)

Indian Standard

INJECTION CONTAINERS AND ACCESSORIES

PART 1 INJECTION VIALS MADE OF GLASS TUBING

1 Scope

This part of ISO 8362 specifies the form, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers shall be made and the performance requirements of those containers.

This part of ISO 8362 applies to colourless or amber glass containers made from borosilicate or soda-lime glass, in the form of glass tubing, whether internally surface-treated or not, and intended for use in the packaging, storage or transportation of products intended for injection.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 719:1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

ISO 720:1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification*

ISO 1101:1983, *Technical drawings — Geometrical tolerancing — Tolerancing of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings*

ISO 4802-1:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802-2:1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

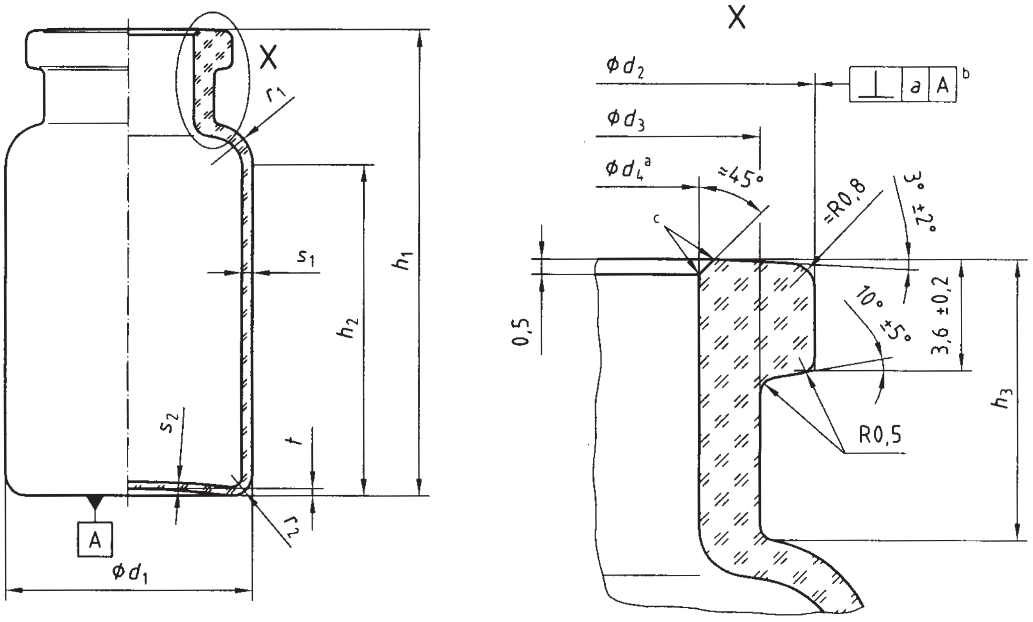
3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4802-1 and ISO 4802-2 apply.

4 Dimensions

The dimensions of injection vials made of glass tubing shall be as shown in Figure 1 and as given in Table 1; the overflow capacity and mass shall be as given in Table 1.

Dimensions in millimetres



[a] The opening of the vial should have a constant diameter, over the entire distance, h_3, i.e. it should exhibit a cylindrical shape. A slightly conical shape can be accepted if the following requirements are fulfilled:

- the truncated cone has the height, h_3;
- the larger diameter is located at the flange;
- the larger diameter does not exceed the smaller one by more than 0,3 mm.

[b] The perpendicularity tolerance a (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

[c] Edges slightly rounded.

Figure 1 — Typical example of injection vial made of glass tubing

Table 1 — Dimensions, overflow capacity and mass

Size designation of injection vial	Overflow capacity ml		a mm	d_1 mm		d_2 mm	d_3 mm	d_4 mm	h_1 mm		h_2 mm	h_3 mm		r_1 mm	r_2 mm	s_1 mm		s_2 mm	t mm	Mass g
		tol.			tol.	$^{+0,2}_{-0,3}$	max.	± 0,2		tol.	min.		tol.	≈	≈		tol.	min.	max.	≈
2R	4	± 0,5	1	16	± 0,15	13	10,5	7	35	± 0,5	22	8	± 0,5	2,5	1,5	1	± 0,04	0,6	0,7	5
4R	6								45		32									6,1
6R	10		1,2	22	± 0,2	20	16,5	12,6	40		26	8,5		3,5	2			0,7		8,3
8R	11,5								45		31									9,4
10R	13,5	± 1		24					45		30	9		4,0						10,2
15R	19								60		45									12,8
20R	26	± 1,5	1,5	30	± 0,25		17,5		55	± 0,7	35	10	± 0,75	5,5	2,5	1,2	± 0,05		1	17,4
25R	32,5								65		45									20
30R	37,5								75		55									22,7

5 Designation

EXAMPLE An injection vial, size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 10R – br – 1

6 Material

Colourless (cl) or amber (br) borosilicate glass or soda-lime glass of one of the following hydrolytic resistance grain classes:

- ISO 720 – HGA 1
- ISO 719 – HGB 3 or ISO 720 – HGA 2

shall be used.

A change in the chemical composition of the glass material or of the colouring oxides should be notified to the user at least nine months in advance.

7 Performance

7.1 Injection vials shall not contain seed or bubbles to an extent which will interfere with the visual examination of the contents.

7.2 Injection vials shall have a sealing surface which is flat and free from ripples or undulations which would affect the sealing performance of the closure.

8 Requirements

8.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of injection vials shall comply with the requirements specified for one of the following hydrolytic resistance container classes:

- ISO 4802 – HC 1
- ISO 4802 – HC 2
- ISO 4802 – HC 3

8.2 Annealing quality

The injection vials shall be annealed so that the maximum residual stress does not produce an optical retardation exceeding 40 nm per millimetre of glass thickness, when the vials are viewed in a strain viewer.

9 Marking

The number of pieces and the designation in accordance with Clause 5 together with the name or symbol of the manufacturer shall be shown on the package.

Further information may be given, subject to agreement.

NATIONAL ANNEX A

(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act,* 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

(*Continued from second cover*)

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 719 : 1985 Glass — Hydrolytic resistance of glass grains at 98° C — Method of test and classification	IS 2303 (Part 1/Sec 1) : 1994 Grading glass or alkalinity: Part 1 Hydrolytic resistance, Section 1 Hydrolytic resistance of glass grains at 98° C — Method of test and classification (*first revision*)	Technically Equivalent
ISO 720 : 1985 Glass — Hydrolytic resistance of glass grains at 121° C — Method of test classification	IS 2303 (Part 1/Sec 2) : 1994 Grading glass or alkalinity: Part 1 Hydrolytic resistance, Section 2 Hydrolytic resistance of glass grains at 121° C — Method of test and classification (*first revision*)	do
ISO 1101 : 1983 Technical drawings — Geometrical tolerancing — Tolerancing of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings	IS 8000 (Part 1) : 1985 Geometrical tolerancing on technical drawings: Part 1 Tolerances of form, orientation, location and run-out and appropriate geometrical definitions (*first revision*)	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 4802-1 : 1988	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification
ISO 4802-2 : 1988	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification

The standard also makes a reference to the BIS certification marking of the product. Details of which is given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

Bureau of Indian Standards

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard alongwith amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of ‘BIS Catalogue’ and ‘Standards: Monthly Additions’.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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